

April 1, 2019

To the Committee at HHS:

The Academic Consortium for Integrative Medicine & Health (the Consortium) commends HHS for its decision to evaluate the evidence for acute and chronic pain care including nonpharmacologic options. The Consortium provides leadership and has extensive experience in incorporating evidence-based approaches such as acupuncture therapy, massage therapy, meditative movement and mind-body therapies for comprehensive, integrative pain care. In response to the HHS call to comment, we respectfully submit the attached statement supported by the current literature.

The Academic Consortium for Integrative Medicine & Health (the Consortium) is the organizational home for the major academic health centers and health systems in North America that have programs in integrative medicine and health. Integrative medicine and health reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing. The Consortium was founded in 1999 by eight academic health centers including Duke University, Harvard University, Stanford University, University of California, San Francisco, University of Arizona, University of Maryland, University of Massachusetts, and the University of Minnesota. Now with over 75 institutional members, the Consortium continues to grow and represents thousands of scientists, educators, clinicians and other health professionals who share an interest in the field of Integrative Medicine and Health. The Consortium's mission is to advance evidence-based integrative medicine and health in research, curricula and sustainable models of clinical care.

We commend the committee's inclusion of conventional and nonpharmacologic therapies to achieve optimal comprehensive pain care.

See

Appendix 1: Consortium Comments

Appendix 2: Consortium Definitions

The Consortium would like to thank the authors for contributing their expertise and time to thoroughly review "Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations" and providing thoughtful recommendations.

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Appendix 1 Consortium Comments HHS

The Academic Consortium for Integrative Medicine & Health (the Consortium) commends the committee's inclusion of nonpharmacologic and conventional therapies to achieve optimal comprehensive pain care and in support recommends the following.

1. Use definitions for nonpharmacologic disciplines that are consistent with legal definitions for regulated professions, and use professional organization definitions for nonregulated approaches. (*Appendix 2* contains current definitions.)
2. Adopt a consistent standard that uses evidence-based benefits and harms for inclusion of medical/health practices into protocols and insurance coverage. Evidence-based standards can be applied to procedures, surgeries, drugs and nonpharmacologic practices including acupuncture therapy, massage therapy, osteopathic and chiropractic manipulation, physical therapy, meditative movement therapies Tai chi and yoga, mind body behavioral interventions, music and relaxation therapies, dietary components, and self-care/self-efficacy strategies.
3. Present nonpharmacologic approaches as a first line of pain care per current recommendations by the CDC,¹ the Army Surgeon General Task Force Report,² the ACP,³ and as part of comprehensive pain care⁴ by the AHRQ,⁵ NIH,⁶ FDA,⁷ and the Joint Commission (TJC).^{8,9} Currently, conventional medical practices are situated as normative and nonpharmacologic options are categorized as 'complementary or nonmainstream', relegated to a second tier of consideration.¹ In order to encourage decisions based on evidence, we support the use of impartial terminology taking into account benefits and harms of procedural, surgical, pharmacologic and nonpharmacologic options.

Specific sections of the HHS report:

2.6 Update Literature

Acupuncture therapy. Over 4 million American adults receive acupuncture annually.⁴⁰ Acupuncture is generally considered safe when performed by a licensed, well-trained practitioner using single-use pre-sterilized needles,¹¹⁻¹⁸ with infrequent minor side effects such as feeling relaxed, elated, tired or having sensation or itching at point of insertion.¹⁵ Rare serious complications such as infection or pneumothorax are directly related to insufficient training.^{16,17,19} In multiple systematic reviews with meta-analyses, acupuncture was effective in reducing post-surgical pain compared to sham acupuncture, controls and usual care with reduction in opioid need with lowered incidence of opioid-related side effects such as nausea, dizziness, sedation, pruritus and urinary retention.²⁰⁻²² Acupuncture is feasible and highly acceptable for adult and pediatric inpatients^{23,24} for acute pain in the emergency department setting^{25,26} and for chronic pain conditions.^{27,28} An individual patient meta-analysis evaluating 39 trials (20,827 patients) of acupuncture for chronic nonspecific back pain, neck pain, shoulder pain, chronic headache or osteoarthritis²⁹ found acupuncture was superior to both sham and no acupuncture controls for each pain condition. The benefits of acupuncture were found to persist over time with only a small decrease, approximately 15%, in treatment effect at one year after randomization. Acupuncture biomechanisms involve complex interrelationships among local tissue mechanoreceptors, propagation of mechanical signals in the connective tissue and neurochemical brain signaling. As with all medical treatments, updating analysis of benefit/harms, clinical indications, frequency, dosage and timing of care is recommended.

¹ CDC Centers for Disease Control and Prevention; **ACP** American College of Physicians; **AHRQ** Agency for Healthcare Research and Quality (US); **NIH** National Institutes of Health National Center for Complementary and Integrative Health; **FDA** US Food and Drug Administration; **TJC** The Joint Commission

Gaps and Recommendations

Gap 1: There are evidence-based modalities and health approaches that remain unknown to the broader medical community and are often overlooked in the management of pain.

- **Recommendation 1a:** Consider evidence-based modalities and health approaches, including acupuncture, mindfulness meditation, movement therapy, art therapy, massage therapy, manipulative therapy, spirituality, yoga, and tai chi, in the treatment of acute and chronic pain, when indicated.
- **Recommendation 1b:** Develop up-to-date Clinical Practice Guidelines (CPG) for the application of evidence-based nonpharmacologic options and health approaches for specific indications.

Gap 2: There is a gap in dissemination of research on biomechanism, efficacy, effectiveness, and cost effectiveness of nonpharmacologic modalities for acute and chronic pain. Generalization of existing research to special populations and strategies to incorporate evidence-based nonpharmacologic modalities into care models will benefit from further research.⁴ Clinicians need clarification and guidance regarding dosage, frequency, and timing of comprehensive strategies that include nonpharmacologic options.

- **Recommendation 2a** Support ongoing research of nonpharmacologic approaches and combinations with pharmacologic means to further clarify therapeutic value, benefits and harms, mechanisms of action, and contribution to the economics of pain care in distinct clinical settings including perioperative surgical pain and in chronic pain conditions and syndromes. Specific research is recommended regarding dosage, timing and frequency of evidence-based interventions and combinations.
- **Recommendation 2b:** Include evidence-based modalities and health approaches as an integrative approach to the treatment of chronic pain.
- **Recommendation 2c:** Conduct further research on supplements such as alpha lipoic acid, L-carnitine transferase, turmeric and vitamin C and their effect on acute and chronic pain management.

Special populations should include multi-morbidity in general and multi-morbidity within specific populations.

Promote the widespread collection of meaningful outcomes data on all interventions (including nonpharmacologic strategies, behavioral health, medications, procedures, and surgeries), to assess effectiveness for relief of suffering and improvement in function.

CDC Guidelines: Opioid prescribing has become more complicated for many reasons. The CDC Guidelines recommend tapering opioid doses to safer levels and incorporating other pharmacologic and nonpharmacologic therapies.¹ It is important to ease the burden on overextended pain medicine prescribers so they can:

- a) spend adequate time to assess the complexity of their patient's problems (as the HHS report recommends)
- b) receive assistance for the many additional recording and instrumental tasks required to prescribe opioids
- c) provide adequate social supports and behavioral health services for their patients
- d) provide vocational counselling for their patients and access to evidence-based group programs that have been shown to optimize productive and meaningful lives for people in pain
- e) provide all these services in the primary language of the patient

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Appendix 2 Definitions

Definition of therapies: need to reflect the legal status of regulated professions in the US, modern research as well as the historical roots of a therapeutic intervention. For example, acupuncture therapy is not based in China alone or as Chinese medicine only but as traditional East Asian medicine. Accurate definitions are essential to inform pragmatic clinical trials (PCTs) that are part of the NIH's vision for bridging the gap between research and care.^{1,2} PCTs are performed in real world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost/time needed to conduct a traditional clinical trial.^{1,3} PCTs are also supported through initiatives at the Center for Medicare & Medicaid (CMS), the Agency for Healthcare Research and Quality (AHRQ), the Patient Centered Outcomes Research Institute (PCORI), Practice-Based Research Networks (PBRNs) and community-based participatory research initiatives across the Federal government.⁴ Hence if a nonpharmacologic intervention is to be studied in a pragmatic trial, how it is legally defined and practiced not as the single mechanical operation but a clinically contextualized approach will best inform stakeholders relying on this HHS report and recommendations.

Suggested

Acupuncture therapy in the U.S. is a state-regulated practice in which practitioners stimulate specific areas or points on the body by application of heat, pressure, electrical stimulation or insertion and manipulation of thin (pre-sterilized, single-use, filiform) needles for the purpose of achieving a therapeutic or prophylactic effect.⁵ Type, location, dosage and combinations of stimulation are based on physiological interrelationships of body organs and tissue with associated points or combination of points, informed by historical medical texts and modern research. Acupuncture therapy may be used to alleviate pain as a stand-alone therapy or as part of comprehensive pain care, as well as to treat other physical, mental and emotional conditions.

Massage therapy is a state-regulated practice that involves manipulation of soft tissue structures of the body to prevent or alleviate pain, spasm, tension, or stress and to promote health and wellbeing.

Osteopathic and Chiropractic manipulation are state-regulated practices. Spinal manipulative therapy (SMT) involves treatment of the spine and pelvic related joints; manipulative therapy (MT) refers to the treatment of other joints in the body including upper and lower extremities. SMT and MT are often associated with high velocity, low amplitude (HVLA) thrust techniques, as well as low velocity, low amplitude (LVLA) or joint mobilization techniques. SMT, MT, HVLA and LVLA are techniques commonly used to improve pain and function, primarily by osteopathic physicians and chiropractors.⁶

Physical therapy is a state-regulated practice utilizing therapeutic exercise, physical modalities, assistive devices, and patient education and training for the preservation, enhancement, or restoration of movement and physical function impaired or threatened by disease, injury, disability or pain.

Meditative movement therapies: Tai chi and Yoga

Tai chi is a low-impact, mind-body exercise originating in China that has become increasingly popular in the West as an effective exercise for rehabilitation related to multiple medical conditions. Tai chi consists of slow prescribed movements with attention to breathing and meditative concentration.

Yoga originated in ancient India and has been adapted in the West. Yoga practice combines attention and meditation (dhyana), breathing (pranayama), and physical postures (asanas) and stretching to promote health and well-being and to help people with health problems manage their health conditions and reduce their symptoms.

2.5 Behavioral Health Approaches

Mind Body Behavioral Interventions and Relaxation Therapies

Mindfulness and meditation-based therapies focus training on moment-to-moment awareness of breathing and attention without judgment to transform perception and relationships to pain and the larger environment. Meditative movement therapies like Tai chi and Yoga utilize intentional movement or positioning with present moment awareness and focus on breathing.⁶

Mindfulness-Based Stress Reduction (MBSR) is an organized course of training in mindfulness skills focusing on moment to moment awareness of breathing and attention without judgment to transform perception and relationships to pain and the larger environment. It is the most studied course of mindfulness meditation.⁷

Relaxation therapies: use physiologic techniques (as in slow diaphragmatic breathing or progressive muscle relaxation) to regulate the sympathetic/parasympathetic balance and reduce symptoms of sympathetic arousal often seen in chronic pain including situational stress, muscle tension and shallow breathing. They also include other directed therapies like guided imagery (use of words depicting calming images and music to evoke positive imaginative scenarios), hypnosis and suggestion (induction of a relaxed but focused state of consciousness receptive to positive suggestion), acceptance and commitment therapy (ACT) (strategies of mindful awareness and acceptance) and music therapy.

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